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NexWave



User's Manual

NexWave

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Zynex Medical

Contact Information

CUSTOMER SERVICE

866-940-7030

Supplies: To order more electrodes or other accessories

Technical Support: Questions or problems with using your device

Device Return: Order a postage paid return envelope to return your device at no charge

MAIN OFFICE

800-495-6670
303-703-4906

Billing Questions: Questions regarding insurance benefits and covered benefits for Durable Medical Equipment (DME) or questions about an Explanation of Benefits form you received in the mail

FAX NUMBER

800-495-6695
855-845-5941

MAILING ADDRESS



Zynex Medical, Inc.
9555 Maroon Circle
Englewood, CO 80112
USA

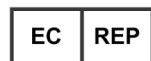
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WEBSITE

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EUROPEAN REPRESENTATIVE



Zynex Europe
Faelledvej 1, Box 19 BDO
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NexWave

Warranty Information

The NexWave device is warranted to be free from defects in material, workmanship, and structural integrity when subjected to normal domestic use and service for five years after the original purchase.

During that time, Zynex Medical, Inc. will replace, at its sole discretion, the NexWave device that has been used in a standard manner. This warranty does not cover misuse or use contrary to the operating instructions supplied.

Warranty obligations are limited to replacement of defective parts and components, at the option of Zynex Medical, Inc. This Warranty is only valid for the original purchaser of this product and will not be honored if the product ownership is transferred or is resold.

To obtain warranty service, please contact Technical Support at the number listed on page 4 of this manual.

NexWave

Electrodes, Batteries, and Cleaning

Electrodes and Skin Care

Proper skin care will help make the use of this device more comfortable and trouble-free. Prior to treatment, wash the areas where the electrodes will be placed with mild soap and water, rinse, and dry the skin thoroughly. If necessary, remove excess body hair.

Sterile electrodes may be required for some post-operative applications.

Follow directions of the prescribing physician.

Battery Power

One 9 V alkaline battery is used. The battery compartment on the back of this device opens by sliding the cover downwards. Rechargeable batteries are not recommended since they have only a short usage time and are not charged while in this device.

Replace battery when the battery icon appears on the display.

Insert the bottom of the battery into the battery compartment first, then press the contacts into position.

The NexWave operates normally even if the 9 V battery is inserted with reverse polarity.

Remove battery if planning to store NexWave.

Please dispose of used batteries properly.

AC Adapter

The NexWave is supplied with an AC adapter that is plugged into the left side of this device and then into a 120 or 230 VAC electrical outlet. Note: The supplied AC adapter, Zynex P/N 200109, mains power requirement is 100-240 VAC, 50-60 Hz, 0.3A maximum. While plugged in, this device is powered from the electrical outlet and not the 9 V battery. The battery does not need to be removed while utilizing the AC adapter.

Device Cleaning

The NexWave case and display window can be cleaned by lightly applying mild soap to a damp soft cloth or paper towel and using it to wipe the surfaces clean. Allow the unit to dry thoroughly before using. Do not spray cleaning solutions directly onto the unit, or immerse it in water or other liquids.

About the NexWave

The NexWave is a multiple-mode stimulator which allows users a choice of treatment options. This device incorporates Interferential Current (IFC), Transcutaneous Electrical Nerve Stimulation (TENS), and Neuromuscular Electrical Stimulation (NMES).

Interferential Current (IFC)

The left channel (channel 1) produces a signal at a frequency of 4000 Hz. A slightly higher frequency (4001-4128 Hz) is produced by the right channel (channel 2). When applied to the skin, the signals from the two channels “interfere” with each other, and create a difference frequency which is felt during treatment. IFC therapy requires the use of both channels (four electrodes).

Transcutaneous Electrical Nerve Stimulation (TENS)

TENS delivers electrical impulses through the skin in the range of 1-125 Hz. TENS treatments can range from 10 minutes to many hours and can be applied as needed for pain relief. Patients can use one or two channels (two or four electrodes) for TENS therapy.

Neuromuscular Electrical Stimulation (NMES)

NMES delivers electrical impulses to muscle motor points at a frequency of 35 Hz. The stimulation is set by the user at a level to cause muscle contraction. There are three different programs to choose from and each program has a preset stimulation “On Time” of 10 seconds. The “rest period” (no stimulation) varies from 10 seconds to 30 seconds depending on which program is used. The 10:10 program setting has a rest period of 10 seconds, the 10:20 program setting has a rest period of 20 seconds, and the 10:30 program setting has a rest period of 30 seconds. For all programs, the stimulation ramp up time is 3 second and the ramp down is 1 seconds. Channel 1 and Channel 2 have the same “On” and “Off” Times and when used together will operate simultaneously.

Important: This device must be ordered or prescribed by a licensed physician.

Safety Information

• Equipment Classification

As per the International Electrotechnical Commission standard IEC 60601-1, and the European standard EN 60601-1, Medical Electrical Equipment, General Requirements for Basic Safety and Essential Performance, the NexWave is classified as follows:

- **Type BF Equipment**

A Type BF piece of equipment is one that provides a particular degree of protection against electric shock, particularly regarding allowable leakage current. Type BF applied part is one that is floating above ground and is isolated from all other parts of the equipment.

- **Medical Device Directive (MDD) Classification**

The NexWave is a Class IIa medical device per the European Medical Device Directive.

- **Internally Powered Equipment**

When the NexWave is powered by the internal, 9 VDC, MN1604, battery it is classified as Internally Powered Equipment.

- **Class II Medical Equipment**

When powered by the external, 12 VDC, medical grade, power supply, the NexWave is classified as Class II Medical Electrical (ME) Equipment. Note: When the external power supply is connected to the NexWave device, the power supply is considered part of the ME equipment.

- **Electromagnetic Compatibility**

Conforms to IEC 60601-1-2.

- **Temperature**

Operating temperature range: 0° - 40° C (32° - 104° F)

Storage temperature range: -20° - 70° C (-4° - 158° F)

- **Water Ingress**

Ordinary equipment. This device does not have protection against ingress of water.

- **Flammable Anesthetics**

This device is not suitable for use in the presence of a flammable anesthetic mixture with air, or in the presence of a flammable anesthetic mixture with oxygen or nitrous oxide.

NexWave

Specifications and Accessories

Interferential Current (IFC)

Amplitude:	0-50 mA
Channel 1 frequency:	4000 Hz
Channel 2 frequency:	4001- 4128 Hz
I/F Modes:	Low-High, Low, Combo
Muscle Mode:	64 Hz, 6 sec. on, 6 sec. off, ramp up 1 sec., and ramp down 0.5 sec.
Waveforms:	Symmetrical biphasic

Transcutaneous Electrical Nerve Stimulation (TENS)

Amplitude:	0-100 mA
Frequency:	1-125 Hz
Pulse Width:	120-300 µs
TENS Modes:	Sweep, Low frequency Modulation, High frequency Modulation
Waveform:	Symmetrical biphasic

Neuromuscular Electrical Stimulation (NMES)

Amplitude:	0-100 mA
Frequency:	35 Hz
Pulse Width:	480 µs
NMES Modes:	30:10, 20:10, 10:10
On-Time:	10 sec.
Off-Time:	30, 20, or 10 sec.
Ramp Up:	3 sec.
Ramp Down:	1 sec.
Waveforms:	Symmetrical biphasic

Other Specifications

Treatment timer:	10 to 90 minutes, in 10 minute increments, with no timer setting
Compliance meter:	Records total usage time in minutes and number of times used
Dimensions:	2.9 x 4.6 x 1.0 in.
Weight:	5.8 oz. including battery
Warranty:	5 year manufacturer's warranty on materials and workmanship Accessories excluded

Accessories

Lead wires:	104203, lead wire, black, with black pins 104204, lead wire, gray, with red pins
Electrodes:	300027, electrodes, 2" diameter, round, pkg. of four 300100, electrodes, sterile, 2" x 2", square, pkg. of four
Power supply:	200109, power supply, medical grade, input 100-240 VAC, 50-60 Hz, 0.3 A max., output 12 VDC, 0.5 A max
Battery:	130010, battery, 9 V, alkaline, MN1604

NexWave

Troubleshooting

Troubleshooting	
Problem	Solution
Unit stays on even after treatment ends.	Press and release Off button to turn unit off. Otherwise unit will shut off automatically after 5 minutes of no stimulation. Alternatively you can start a new treatment session after the last one ends.
Cannot increase level from its current setting.	Press and release Unlock button to unlock this safety feature. Then increase stimulation to the desired level/intensity. Intensity level is always locked after 20 seconds of key press inactivity.
Do not feel the IF beat frequency in the center of the four electrodes.	Check that the lead wires are connected correctly to the electrodes (red opposite each other, black opposite each other).
Display shows “Check Connections” (electrode alarm).	Check electrode skin contact. Electrodes should be fresh and stick well. Use water if necessary to soften the gel for better contact. Verify that all four electrodes are connected to lead wires and that both lead wires are connected to the unit. Connect the bare metal pins together to short-circuit the outputs. If the electrode alarm ceases the problem is with the electrode connection integrity.
When the ON button is pressed, a flashing “Lock” icon appears on the display and the NexWave remains unresponsive.	Press and hold the UNLOCK button for 20 seconds or until the “Lock” icon on the display disappears.

Safety Information

- **Mode of Operation**
This device is suitable for continuous operation.

- **Symbols**



Safety symbols shown on this device above are defined below.

 **On/Off.** This symbol indicates that the labeled switch electronically cycles the DC power on and off for part of the equipment. Note: To disconnect the external power supply, unplug the power cord of the supplied AC adapter from the AC mains outlet.

 **General Warning Sign.** Follow warnings stated in the instruction manual to prevent potential hazards.

 **Refer to Instruction Manual/Booklet.** The operator must read, understand, and follow all instructions in the accompanying document including all warnings, cautions, and precautions before using this medical device.

 **Type BF Equipment.** This symbol indicates that the patient applied parts (electrodes) are Type BF (floating from ground) offering the user a specific level of safety.



Waste Electrical and Electronic Equipment (WEEE). This product may contain substances known to be hazardous to the environment or to human health. It should be disposed of properly (for example, at your local waste collection administration or recycling plant) and in accordance with local ordinances.

Service and Calibration

- Do not remove the cover. There are no user serviceable parts. Refer all service to authorized personnel. No modification of the equipment is allowed.
- No preventative inspections are required. Factory testing and calibration ensure equipment accuracy and response.

NexWave

Precautions and Adverse Reactions All Modes (IFC, TENS, NMES)

Precautions

- Isolated cases of skin irritation may occur at the site of the electrode placement following long-term application.
- Effectiveness is highly dependent upon patient selection by a person qualified in management of pain patients.
- Safety of powered muscle stimulators for use during pregnancy has not been established.
- Caution should be used for patients with suspected or diagnosed heart problems.
- Caution should be used for patients with suspected or diagnosed epilepsy.
- Caution should be used in the presence of the following:
 1. When there is a tendency to hemorrhage following acute trauma or fracture.
 2. Following recent surgical procedures when muscle contraction may disrupt the healing process.
 3. Over the menstruating or pregnant uterus
 4. Over the areas of the skin which lack normal sensation.
- Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrically conductive medium. The irritation can usually be reduced by using an alternate conductive medium, or alternate electrode placement.
- Electrode placement and stimulation settings should be based on the guidance of the prescribing physician.
- This device should be kept out of reach of children.
- This device should be used only with the leads and electrodes recommended for use by the manufacturer.
- This device should not be used while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the user at undue risk of injury.

Adverse Reactions

- Skin irritation and burns beneath the electrodes are potential adverse reactions.

NexWave

Warnings

Neuromuscular Electrical Stimulation (NMES)

Warnings (Continued)

- Stimulation should not be applied over the neck or mouth. Severe spasm of the laryngeal and pharyngeal muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing.
- Stimulation should not be applied transthoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias.
- Stimulation should not be applied transcranially.
- Stimulation should not be applied over swollen, infected, or inflamed areas of skin, eruptions, e.g. phlebitis, thrombophlebitis, varicose veins, etc.
- Stimulation should not be applied over, or in proximity to, cancerous lesions.
- This device is capable of generating currents and voltages in excess of 10 mA RMS and 10 V RMS, respectively. A yellow LED indicator is provided next to each lead wire connector to show that the unit is delivering energy for any non-zero value of stimulation output (1-100 mA).
- Simultaneous connection of a patient to high frequency surgical equipment may result in burns at the site of the stimulator electrodes and possible damage to the stimulator.
- Operations within close proximity (within one meter) of shortwave or microwave therapy equipment may produce instability in the stimulation output.

Safety References

Zynex Medical, Inc. is only responsible for the safety, reliability and function of this device when repairs and adjustments have been made by persons authorized by Zynex Medical, Inc., and this device is used in accordance with the user's manual. Repairs and technical safety tests shall only be performed by authorized personnel.

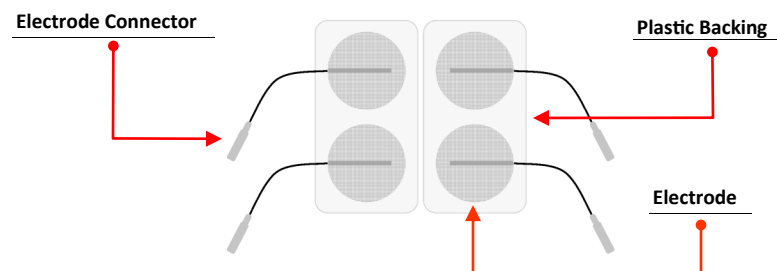
NexWave

Electrode and Lead Wire Setup

Step 1

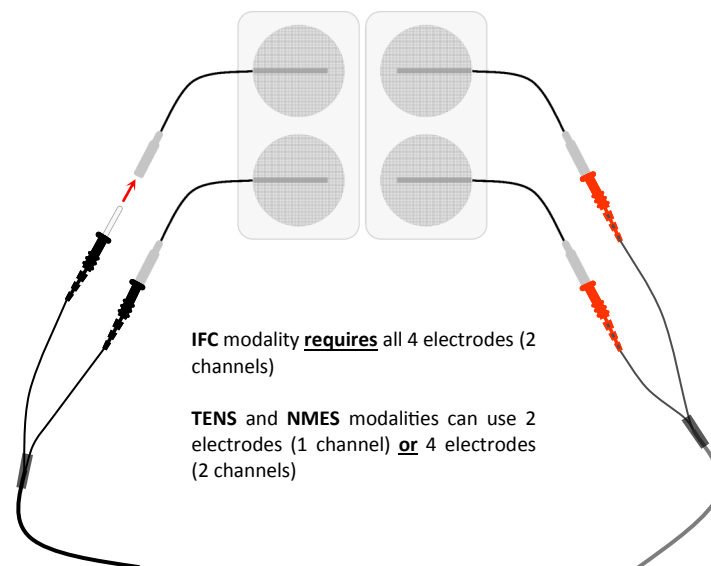
Open electrode package and remove electrodes from package. Keep electrodes on plastic backing.

Note: Zynex Medical electrodes are recommended for use with the NexWave. See additional accessories on page 43.



Step 2

Insert lead wire pin connectors into electrode connectors as shown below. **RED** lead wire connectors on one side and **BLACK** lead wire connectors on the other side.

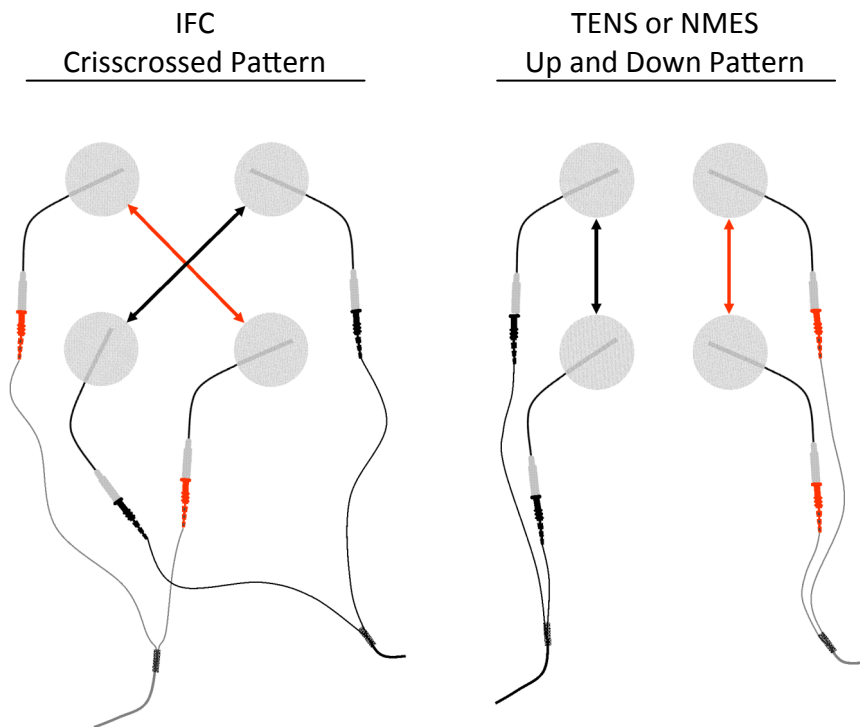


Step 3 Remove each electrode from the plastic backing and place on the treatment site according to the type of modality selected.

Electrode Arrangement

When using the **IFC** modality, **RED** and **BLACK** lead wires must be placed in a crisscrossed pattern as shown in the diagram below.

TENS or NMES: Using both channels and crisscrossing the electrodes is optional.



Warnings (Continued)

The maximum output power that the NexWave can produce is 0.168 W per channel into a 1000 Ω load, 0.336 W total.

- Maximum peak output voltage (500 Ω load) = 50 V
 - Maximum peak output current (500 Ω load) = 100 mA
 - Maximum peak output voltage (1 K Ω load) = 100 V
 - Maximum peak output current (1 K Ω load) = 100 mA
 - Maximum peak output voltage (2 K Ω load) = 100 V
 - Maximum peak output current (2 K Ω load) = 50 mA
 - Pulse width range: 480 μ s
 - Pulse frequency range: 35 Hz
 - Maximum RMS voltage (500 Ω load) = 6.48 V
 - Maximum RMS current (500 Ω load) = 12.96 mA
 - Maximum output power (500 Ω load) = 0.084 W per channel
 - Maximum RMS voltage (1 K Ω load) = 12.96 V
 - Maximum RMS current (1 K Ω load) = 12.96 mA
 - Maximum output power (1 K Ω load) = 0.168 W per channel
 - Maximum RMS voltage (2 K Ω load) = 12.96 V
 - Maximum RMS current (2 K Ω load) = 6.48 mA
 - Maximum output power (2 K Ω load) = 0.084 W per channel
-
- The safety of NMES devices for use during pregnancy or birth has not been established.
 - This device is not effective for pain of central origin. (This includes headache.)
 - This device should only be used under the continued supervision of a physician.
 - This device does not have curative value.
 - This device offers symptomatic treatment such as suppressing the sensation of pain which would otherwise serve as a protective mechanism.
 - The user must keep this device out of the reach of children.
 - Electronic monitoring equipment (such as ECG monitors and ECG alarms) may not operate properly when this device is in use.
 - The long-term effects of chronic electrical stimulation are unknown.
 - Stimulation should not be applied over the carotid sinus nerves, particularly in patients with known sensitivity to the carotid sinus reflex.

NexWave

Indications for Use Neuromuscular Electrical Stimulation (NMES)

Indications

- Muscle re-education
- Prevention or retardation of disuse atrophy
- Increasing local blood circulation
- Maintaining or increasing range of motion
- Relaxation of muscle spasms

Contraindications

- This stimulator should **not** be used on patients with a cardiac demand pacemaker.
- Electrodes should **not** be placed so that current will be applied to the carotid sinus (neck) region or transcranially (through the head).
- This stimulator should **not** be used whenever pain syndromes are undiagnosed until etiology is established.

Warnings

- When using the separate external power supply, this medical electrical device does not incorporate a power switch to isolate the system from the AC mains. Unplug the power cord of the AC adapter from the AC mains outlet in order to positively disconnect from the AC mains. Ensure that the AC outlet is easily accessible.
- This device is capable of generating current densities for electrodes exceeding 2 mA rms/cm² which may require special attention of the operator.
- Do not exceed 0.5 W/cm² with recommended electrodes, assuming a load of 1000 Ω.
 - 1" round: Maximum stimulation setting = 100 mA
 - 2" round: Maximum stimulation setting = 100 mA
 - 2" square: Maximum stimulation setting = 100 mA
- Output waveform/power information:
When delivering stimulation energy, the NexWave in NMES mode is a constant current output device. Therefore its output voltage, current, and power are dependent upon the load as well as the pulse width and frequency of the output waveform. The maximum peak voltage that the NexWave can produce is 100 V (1000 Ω load).

NexWave

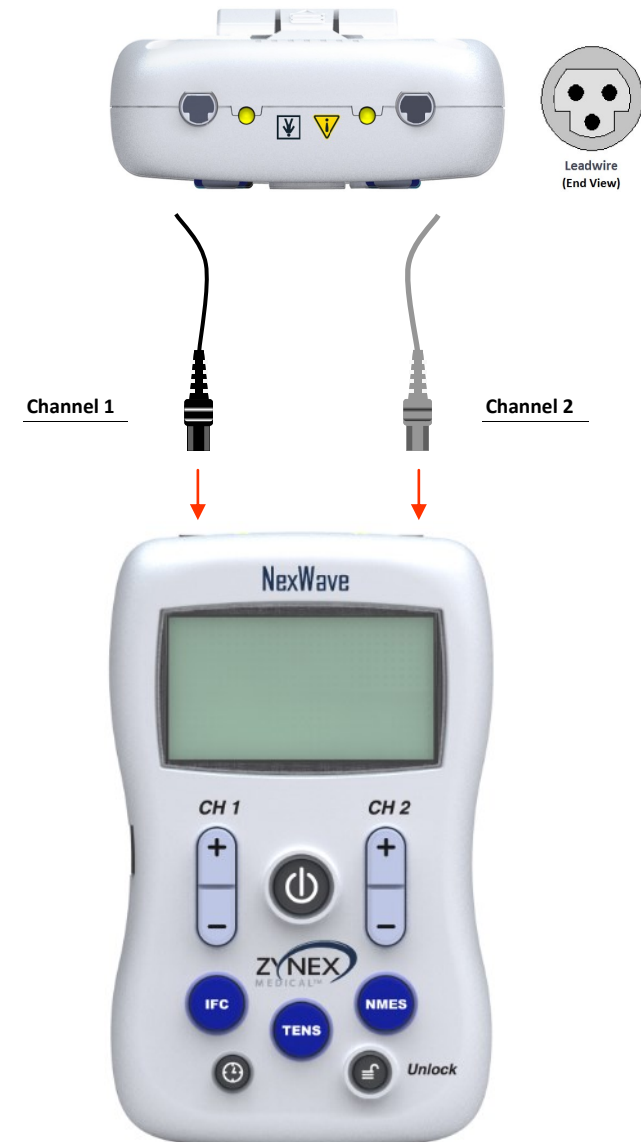
Electrode and Lead Wire Setup (continued)

Step 4

Plug lead wires into the top of the NexWave while carefully observing their orientation. The IFC modality requires both lead wires to be connected (channel 1 & 2). TENS and NMES modalities require one or both lead wires.

Step 5

Proceed to page 16 to start treatment or page 12 to program device.

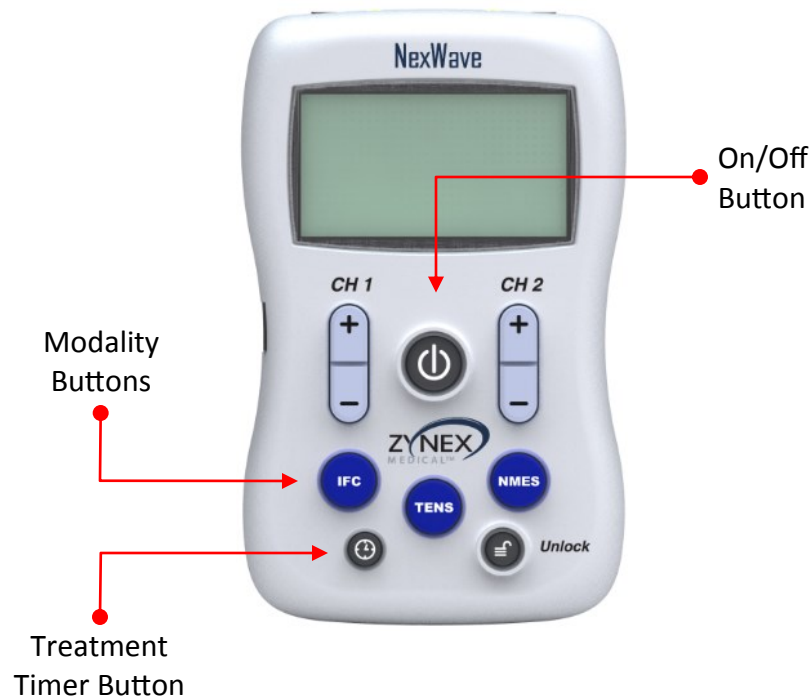


NexWave

Device Programming Instructions

1. Place electrodes on the skin prior to turning on this device.
2. Turn device on by pressing the black On/Off button
3. Select desired Modality by pressing the “IFC”, “TENS”, or “NMES” button once.
4. Continue to press the selected modality button until arrow is next to desired program.
5. Press Treatment Timer button until desired treatment time is set on screen.

Device is now ready to use.



NexWave

Warnings

Transcutaneous Electrical Nerve Stimulation (TENS)

Warnings (Continued)

- Stimulation should not be applied transthoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias.
- Stimulation should not be applied transcerebrally.
- Stimulation should not be applied over swollen, infected, or inflamed areas of skin, eruptions, e.g. phlebitis, thrombophlebitis, varicose veins, etc.
- Stimulation should not be applied over, or in proximity to, cancerous lesions.
- This device is capable of generating currents and voltages in excess of 10 mA RMS and 10 V RMS, respectively. A yellow LED indicator is provided next to each lead wire connector to show that the unit is delivering energy for any non-zero value of stimulation output (1-100 mA).
- Simultaneous connection of a patient to high frequency surgical equipment may result in burns at the site of the stimulator electrodes and possible damage to the stimulator.
- Operations within close proximity (within one meter) of shortwave or microwave therapy equipment may produce instability in the stimulation output.

Safety References

Zynex Medical, Inc. is only responsible for the safety, reliability and function of this device when repairs and adjustments have been made by persons authorized by Zynex Medical, Inc., and this device is used in accordance with the user's manual. Repairs and technical safety tests shall only be performed by authorized personnel.

NexWave

Warnings

Transcutaneous Electrical Nerve Stimulation (TENS)

Warnings (Continued)

- Maximum peak output voltage (500 Ω load) = 50 V
- Maximum peak output current (500 Ω load) = 100 mA
- Maximum peak output voltage (1 K Ω load) = 100 V
- Maximum peak output current (1 K Ω load) = 100 mA
- Maximum peak output voltage (2 K Ω load) = 100 V
- Maximum peak output current (2 K Ω load) = 50 mA
- Pulse width range: 120 - 300 μ s
- Pulse frequency range: 1 - 125 Hz
- Maximum RMS voltage (500 Ω load) = 7.07 V
- Maximum RMS current (500 Ω load) = 14.14 mA
- Maximum output power (500 Ω load) = 0.10 W per channel
- Maximum RMS voltage (1 K Ω load) = 14.14 V
- Maximum RMS current (1 K Ω load) = 14.14 mA
- Maximum output power (1 K Ω load) = 0.20 W per channel
- Maximum RMS voltage (2 K Ω load) = 14.14 V
- Maximum RMS current (2 K Ω load) = 7.07 mA
- Maximum output power (2 K Ω load) = 0.10 W per channel
- The safety of TENS devices for use during pregnancy or birth has not been established.
- This device is not effective for pain of central origin. (This includes headache.)
- This device should only be used under the continued supervision of a physician.
- This device does not have curative value.
- This device offers symptomatic treatment such as suppressing the sensation of pain which would otherwise serve as a protective mechanism.
- The user must keep this device out of the reach of children.
- Electronic monitoring equipment (such as ECG monitors and ECG alarms) may not operate properly when this device is in use.
- The long-term effects of chronic electrical stimulation are unknown.
- Stimulation should not be applied over the carotid sinus nerves, particularly in patients with known sensitivity to the carotid sinus reflex.
- Stimulation should not be applied over the neck or mouth. Severe spasm of the laryngeal and pharyngeal muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing.

NexWave

Preprogrammed Modes

Interferential Current (IFC)

Mode	Description
Low-High	The frequency of channel 2 sweeps between 4001 Hz and 4128 Hz every 15 seconds, while the channel 1 frequency remains fixed at 4000 Hz.
Low	The frequency of channel 2 sweeps between 4001 Hz and 4010 Hz every 15 seconds, while the channel 1 frequency remains fixed at 4000 Hz.
Combo	Combo consists of three 2 minute cycles which repeat over the duration of the treatment. 1st cycle - Low Mode: as described above. 2nd cycle - High Mode: like Low Mode, but channel 2 sweeps between 4064 Hz and 4128 Hz. 3rd cycle - Muscle Mode: The frequency of channel 2 is fixed at 4064 Hz, and the frequency of channel 1 is fixed at 4000 Hz. Both channels are cycled on and off simultaneously at 6 second intervals.

Transcutaneous Electrical Nerve Stimulation (TENS)

Mode	Description
Sweep	The frequency is decreased linearly from 125 Hz to 11 Hz over a 4 second span. During this time, the pulse width is increased linearly from 120 μ s to 300 μ s. Then the frequency is decreased from 10 Hz to 1 Hz over a two second span. The pulse width is constant at 300 μ s. Then the frequency is increased linearly from 1 Hz to 10 Hz over a two second span. The pulse width is constant at 300 μ s. Then the frequency is increased linearly from 11 Hz to 125 Hz over a four second span. During this time, the pulse width is decreased linearly from 300 μ s to 120 μ s.
Low frequency Modulation	Frequency sweeps between 66.7-100 Hz and back again over 12 seconds. Pulse width linearly decreases to 150 μ s when frequency is sweeping up and increases back up to the default pulse width of 300 μ s when frequency is sweeping down.
High frequency Modulation	Same as Lmd, but with a frequency shift interval of 2 seconds.

NexWave

Preprogrammed Modes

Neuromuscular Electrical Stimulation (NMES)

Mode	Description
30:10	Preset 10 seconds on and 30 seconds off time, 35 Hz frequency, 480 μ s pulse width, 3 second ramp-up, 1 second ramp-down, both channels cycle simultaneously.
20:10	Same as above, but with a 20 second off time.
10:10	Same as above, but with a 10 second off time.

NexWave

Indications for Use

Transcutaneous Electrical Nerve Stimulation (TENS)

Indications

- Management and symptomatic relief of chronic intractable, post-traumatic and post-surgical pain.

Contraindications

- This stimulator should **not** be used on patients with a cardiac demand pacemaker.
- Electrodes should **not** be placed so that current will be applied to the carotid sinus (neck) region or transcerebrally (through the head).
- This stimulator should **not** be used whenever pain syndromes are undiagnosed until etiology is established.

Warnings

- When using the separate external power supply, this medical electrical device does not incorporate a power switch to isolate the system from the AC mains. Unplug the power cord of the AC adapter from the AC mains outlet in order to positively disconnect from the AC mains. Ensure that the AC outlet is easily accessible.
- This device is capable of generating current densities for electrodes exceeding 2 mA RMS/cm² which may require special attention of the operator.
- Do not exceed 0.5 W/cm² with recommended electrodes, assuming a load of 1000 Ω .
 - 1" round: Maximum stimulation setting = 100 mA
 - 2" round: Maximum stimulation setting = 100 mA
 - 2" square: Maximum stimulation setting = 100 mA
- Output waveform/power information:
When delivering stimulation energy, the NexWave in TENS mode is a constant current output device. Therefore its output voltage, current, and power are dependent upon the load as well as the pulse width and frequency of the output waveform. The maximum peak voltage that the NexWave can produce is 100 V (1000 Ω load). The maximum peak current that the NexWave can produce is 100 mA (1000 Ω load). The maximum output power that the NexWave can produce is 0.15 W per channel into 1000 Ω load, 0.30 W total.

NexWave

Warnings Interferential Current (IFC)

Warnings (Continued)

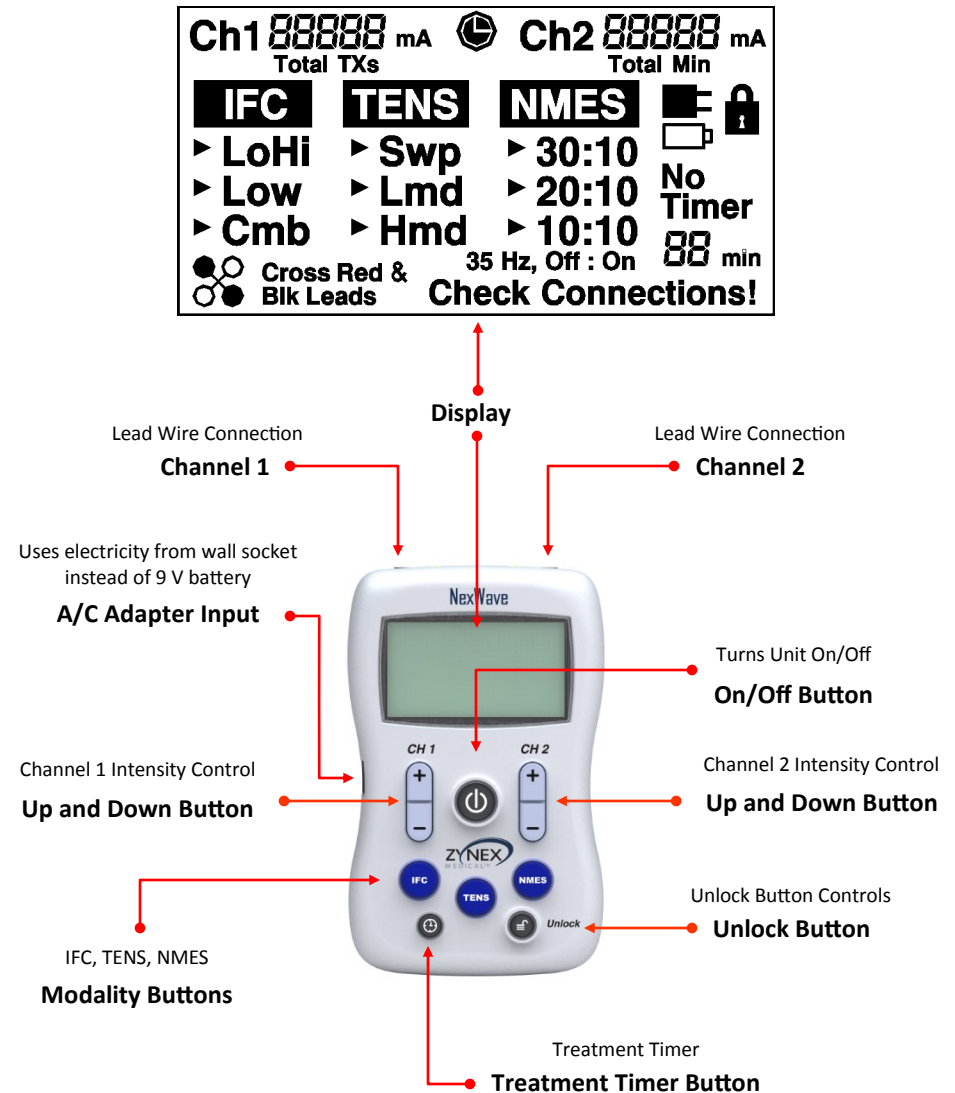
- Stimulation should not be applied transcranially.
- Stimulation should not be applied over swollen, infected, or inflamed areas of skin, eruptions, e.g. phlebitis, thrombophlebitis, varicose veins, etc.
- Stimulation should not be applied over, or in proximity to, cancerous lesions.
- This device is capable of generating currents and voltages in excess of 10 mA RMS and 10 V RMS, respectively. A yellow LED indicator is provided next to each lead wire connector to show that the unit is delivering energy for any non-zero value of stimulation output (1-50 mA).
- Simultaneous connection of a patient to high frequency surgical equipment may result in burns at the site of the stimulator electrodes and possible damage to the stimulator.
- Operations within close proximity (within one meter) of shortwave or microwave therapy equipment may produce instability in the stimulation output.

Safety References

Zynex Medical, Inc. is only responsible for the safety, reliability and function of this device when repairs and adjustments have been made by persons authorized by Zynex Medical, Inc., and this device is used in accordance with the user's manual. Repairs and technical safety tests shall only be performed by authorized personnel.

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Device Controls



Start Treatment:

Before starting treatment electrodes must be placed on the treatment site and lead wires and electrodes connected to this device. See pages 9-11 and 17-31 for examples.

1. Turn NexWave on by pressing On/Off button once.
2. Increase intensity by pressing Channel 1 *Up button* until a strong but comfortable stimulation level is felt. Repeat for Channel 2 if both lead wires are attached and device is in TENS or NMES mode.
3. Once desired level of stimulation is set, the unit will automatically shut off at the preset treatment time shown on the display. If Treatment Timer has been set to “No Timer” then this device will need to be shut off manually. *Refer to Programming Instructions on page 12 to adjust Treatment Timer.*
4. To turn off device manually, press the On/Off button.

During Treatment:

IMPORTANT: *Button controls lock after 20 seconds of inactivity. To unlock button controls, press Unlock button.*

Increase Intensity:

To increase intensity, press the Up Intensity button for the desired channel until the preferred level of stimulation is felt. While in IFC mode, pressing either Up Intensity button will increase the stimulation level.

Decrease Intensity:

To decrease intensity, press the Down Intensity button for the desired channel until the preferred level of stimulation is felt. While in IFC mode, pressing either Down Intensity button will decrease the stimulation level.

Display Alerts:

Check Connections: Lead wire(s) and/or electrode(s) may not be attached properly. Check all connections and try again (see page 42). If problem persists, call Technical Support (see page 4).

Low Battery: Replace battery immediately or connect the A/C adapter.

Locked: Stimulation level and mode cannot be changed until Unlock button is pressed.

Warnings (Continued)

- Maximum peak output voltage (500 Ω load) = 25 V
 - Maximum peak output current (500 Ω load) = 50 mA
 - Maximum peak output voltage (1 K Ω load) = 50 V
 - Maximum peak output current (1 K Ω load) = 50 mA
 - Maximum peak output voltage (2 K Ω load) = 50 V
 - Maximum peak output current (2 K Ω load) = 25 mA
 - Frequency: 4000 Hz nominal
 - Duty Cycle: 100%
 - Maximum RMS voltage (500 Ω load) = 25 V
 - Maximum RMS current (500 Ω load) = 50 mA
 - Maximum output power (500 Ω load) = 1.25 W per channel
 - Maximum RMS voltage (1 K Ω load) = 50 V
 - Maximum RMS current (1 K Ω load) = 50 mA
 - Maximum output power (1 K Ω load) = 2.5 W per channel
 - Maximum RMS voltage (2 K Ω load) = 50 V
 - Maximum RMS current (2 K Ω load) = 25 mA
 - Maximum output power (2 K Ω load) = 1.25 W per channel
-
- The safety of Interferential devices for use during pregnancy or birth has not been established.
 - This device is not effective for pain of central origin. (This includes headache.)
 - This device should only be used under the continued supervision of a trained physician.
 - This device does not have curative value.
 - This device offers symptomatic treatment such as suppressing the sensation of pain which would otherwise serve as a protective mechanism.
 - The user must keep this device out of the reach of children.
 - Electronic monitoring equipment (such as ECG monitors and ECG alarms) may not operate properly when this device is in use.
 - The long-term effects of chronic electrical stimulation are unknown.
 - Stimulation should not be applied over the carotid sinus nerves, particularly in patients with known sensitivity to the carotid sinus reflex.
 - Stimulation should not be applied over the neck or mouth. Severe spasm of the laryngeal and pharyngeal muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing.
 - Stimulation should not be applied transthoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias.

NexWave

Indications for Use
Interferential Current (IFC)

Indications

- Management and symptomatic relief of chronic intractable, post-traumatic and post-surgical pain.

Contraindications

- This stimulator should **not** be used on patients with a cardiac demand pacemaker.
- Electrodes should **not** be placed so that current will be applied to the carotid sinus (neck) region or transcerebrally (through the head).
- This stimulator should **not** be used whenever pain syndromes are undiagnosed until etiology is established.

Warnings

- When using the separate external power supply, this medical electrical device does not incorporate a power switch to isolate the system from the AC mains. Unplug the power cord of the AC adapter from the AC mains outlet in order to positively disconnect from the AC mains. Ensure that the AC outlet is easily accessible.
- This device is capable of generating current densities for electrodes exceeding 2 mA RMS/cm² which may require special attention of the operator.
- Do not exceed 0.5 W/cm² with recommended electrodes, assuming a load of 1000 Ω .
 - 1" round: Maximum stimulation setting = 50 mA
 - 2" round: Maximum stimulation setting = 50 mA
 - 2" square: Maximum stimulation setting = 50 mA
- Output waveform/power information:
When delivering stimulation energy, the NexWave in IFC mode is a constant current output device. Therefore, its output voltage, current, and power are dependent upon the load as well as the pulse width and frequency of the output waveform. Using the supplied AC adapter to power the unit, the maximum peak voltage that the NexWave can produce is 50 V (1000 Ω load). The maximum peak current that the NexWave can produce is 50 mA (1000 Ω load). The maximum output power that the NexWave can produce is 2.5 W per channel into a 1000 Ω load, 5 W total.

Radicular Back Pain-Sciatica

PAIN CONTROL - TENS ONLY

INTENSITY LEVEL:

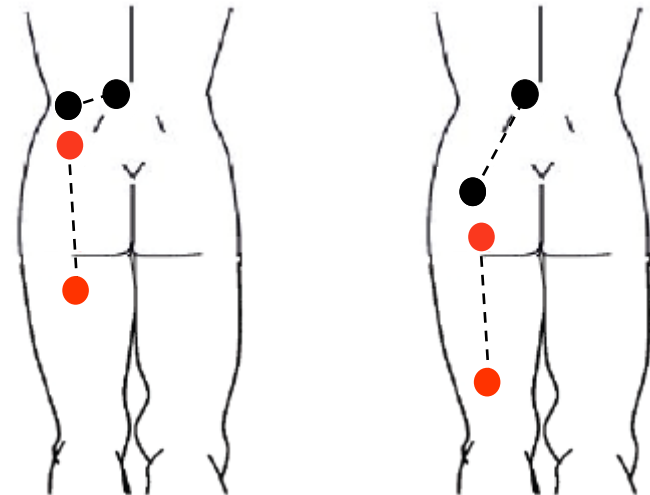
The stimulation level should be set to a strong, but comfortable strength.

DEVICE SET-UP:

Modality	Mode	Suggested Treatment
TENS	Swp, Lmd, Hmd	As needed

ELECTRODE PLACEMENT

Place one set of electrodes for one channel close to the spine and follow the pain route as shown below. The other channel electrodes should be placed to follow pain route down the leg when pain is felt below the low back as shown below.



Option 1

Option 2

Lumbar Back

PAIN CONTROL

INTENSITY LEVEL:

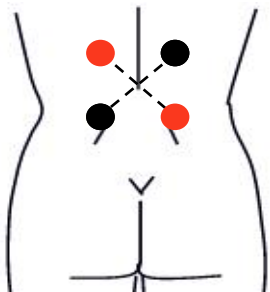
The stimulation level should be set to a strong, but comfortable strength.

DEVICE SET-UP:

Modality	Mode	Treatment Time
IFC	LoHi, Low, Cmb	40 minutes 4 times/day
TENS	Swp, Lmd, Hmd	As needed

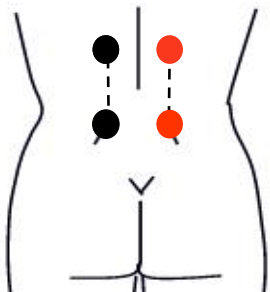
ELECTRODE PLACEMENT

Electrodes should surround the targeted treatment site with area of pain located in the center of the electrode area.



IFC Modality

Place the electrodes with the **RED** and **BLACK** ends of the lead wires according to pattern depicted on figure to the left.



TENS Modality

Place the electrodes with the **RED** and **BLACK** ends of the lead wires according to pattern depicted on figure to the left.

Using both channels and crisscrossing the electrodes is optional when using the TENS modality.

Muscle Spasm

SPASM REDUCTION

Muscle spasm may be reduced by intentionally fatiguing the associated muscle or muscle group.

INTENSITY LEVEL:

The stimulation level should be set to a strong, but comfortable strength.

DEVICE SET-UP:

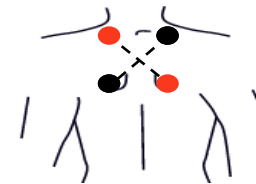
Modality	Mode	Treatment Time
IFC	Cmb	40 minutes 3 to 4 times/day
NMES	10:10 on: off time	40 minutes 3 to 4 times/day

ELECTRODE PLACEMENT

Electrodes should surround the targeted treatment site with area of pain located in the center of the electrode area.

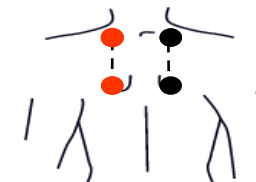
IFC Modality

Place the electrodes with the **RED** and **BLACK** ends of the lead wires according to pattern depicted on figure below.



NMES Modality

Place the electrodes with the **RED** and **BLACK** ends of the lead wires according to pattern depicted on figure below.



Post-Operative Knee

PAIN RELIEF & EDEMA REDUCTION

Post-operative pain and swelling may be reduced by the application of electrical stimulation immediately after surgery and continuing as needed.

INTENSITY LEVEL:

The stimulation level should be set to a strong, but comfortable strength.

DEVICE SET-UP:

Modality	Mode	Treatment Time
IFC	Cmb	40 minutes 4 times/day
TENS	Swp, Lmd or Hmd	As needed for pain & swelling

ELECTRODE PLACEMENT

When applying electrodes in the operating room, sterile electrodes must be used and placed away from incisions as shown below. Electrodes applied outside the operating room do not need to be sterile and should be placed around the bandaged area in the pattern shown below. *Electrodes should surround the targeted treatment site with area of pain located in the center of the electrode area.*

IFC Modality

Place the electrodes with the **RED** and **BLACK** ends of the lead wires according to pattern depicted on figure below.



TENS Modality

Place the electrodes with the **RED** and **BLACK** ends of the lead wires according to pattern depicted on figure below. *Crisscrossing the electrodes is optional when using TENS modality.*



Cervical / Upper Back

PAIN CONTROL

INTENSITY LEVEL:

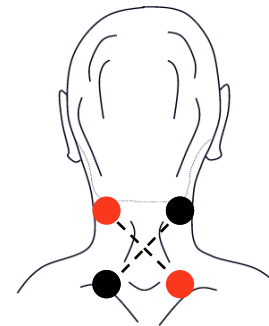
The stimulation level should be set to a strong, but comfortable strength.

DEVICE SET-UP:

Modality	Mode	Treatment Time
IFC	LoHi, Low, Cmb	40 minutes 4 times/day
TENS	Swp, Lmd, Hmd	As needed

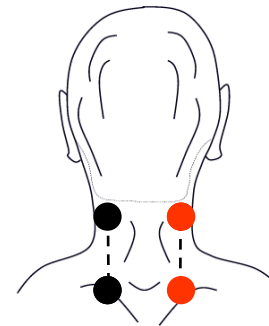
ELECTRODE PLACEMENT

Electrodes should surround the targeted treatment site with area of pain located in the center of the electrode area.



IFC Modality

Place the electrodes with the **RED** and **BLACK** ends of the lead wires according to pattern depicted on figure to the left.



TENS Modality

Place the electrodes with the **RED** and **BLACK** ends of the lead wires according to pattern depicted on figure to the left.

Using both channels and crisscrossing the electrodes is optional when using the TENS modality.

Thoracic Back

PAIN CONTROL

INTENSITY LEVEL:

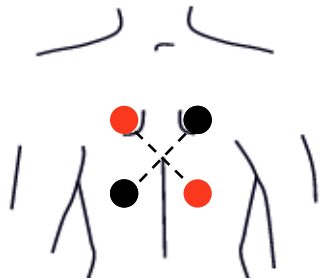
The stimulation level should be set to a strong, but comfortable strength.

DEVICE SET-UP:

Modality	Mode	Treatment Time
IFC	LoHi, Low, Cmb	40 minutes 4 times/day
TENS	Swp, Lmd, Hmd	As needed

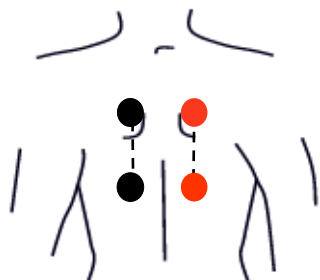
ELECTRODE PLACEMENT

Electrodes should surround the targeted treatment site with area of pain located in the center of the electrode area.



IFC Modality

Place the electrodes with the **RED** and **BLACK** ends of the lead wires according to pattern depicted on figure to the left.



TENS Modality

Place the electrodes with the **RED** and **BLACK** ends of the lead wires according to pattern depicted on figure to the left.

Using both channels and crisscrossing the electrodes is optional when using the TENS modality.

Foot

PAIN CONTROL

INTENSITY LEVEL:

The stimulation level should be set to a strong, but comfortable strength.

DEVICE SET-UP:

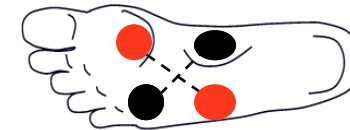
Modality	Mode	Treatment Time
IFC	LoHi, Low, Cmb	40 minutes 4 times/day
TENS	Swp, Lmd, Hmd	As needed

ELECTRODE PLACEMENT

Electrodes should surround the targeted treatment site with area of pain located in the center of the electrode area.

IFC Modality

Place the electrodes with the **RED** and **BLACK** ends of the lead wires according to pattern depicted on figure below.



TENS / NMES Modality

Place the electrodes with the **RED** and **BLACK** ends of the lead wires according to pattern depicted on figure below. *Using both channels and crisscrossing the electrodes is optional when using the TENS modality.*



Ankle

PAIN CONTROL

INTENSITY LEVEL:

The stimulation level should be set to a strong, but comfortable strength.

DEVICE SET-UP:

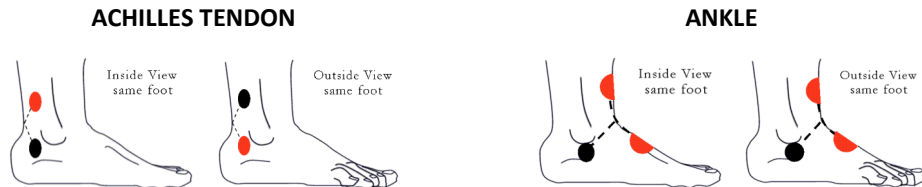
Modality	Mode	Treatment Time
IFC	LoHi, Low, Cmb	40 minutes 4 times/day
TENS	Swp, Lmd, Hmd	As needed

ELECTRODE PLACEMENT

Electrodes should surround the targeted treatment site with area of pain located in the center of the electrode area.

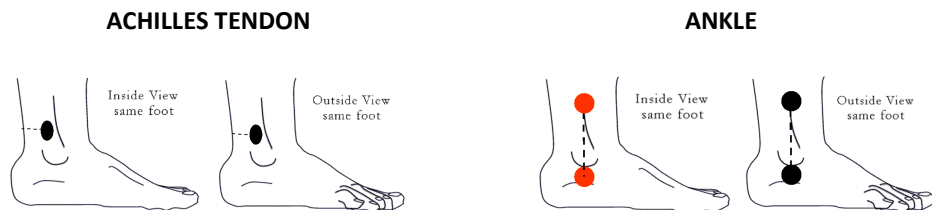
IFC Modality

Place the electrodes with the **RED** and **BLACK** ends of the lead wires according to pattern depicted on figure below.



TENS Modality

Place the electrodes with the **RED** and **BLACK** ends of the lead wires according to pattern depicted on figure below. *Crisscrossing the electrodes is optional when using the TENS modality.*



Shoulder

PAIN CONTROL

INTENSITY LEVEL:

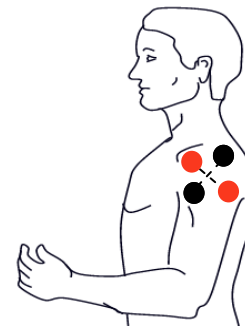
The stimulation level should be set to a strong, but comfortable strength.

DEVICE SET-UP:

Modality	Mode	Treatment Time
IFC	LoHi, Low, Cmb	40 minutes 4 times/day
TENS	Swp, Lmd, Hmd	As needed

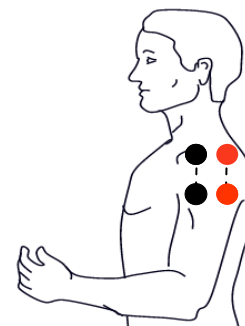
ELECTRODE PLACEMENT

Electrodes should surround the targeted treatment site with area of pain located in the center of the electrode area.



IFC Modality

Place the electrodes with the **RED** and **BLACK** ends of the lead wires according to pattern depicted on figure to the left.



TENS Modality

Place the electrodes with the **RED** and **BLACK** ends of the lead wires according to pattern depicted on figure to the left.

Using both channels and crisscrossing the electrodes is optional when using the TENS modality.

Elbow

PAIN CONTROL

INTENSITY LEVEL:

The stimulation level should be set to a strong, but comfortable strength.

DEVICE SET-UP:

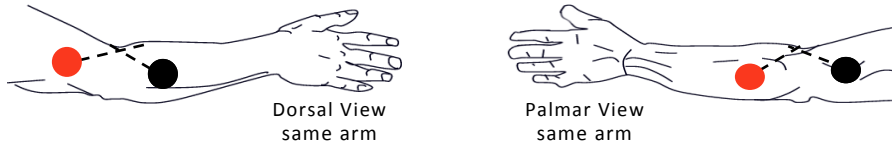
Modality	Mode	Treatment Time
IFC	LoHi, Low, Cmb	40 minutes 4 times/day
TENS	Swp, Lmd, Hmd	As needed

ELECTRODE PLACEMENT

Electrodes should surround the targeted treatment site with area of pain located in the center of the electrode area.

IFC Modality

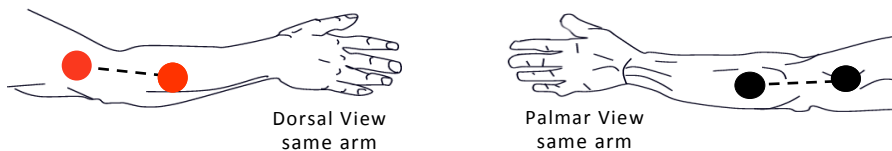
Place the electrodes with the **RED** and **BLACK** ends of the lead wires according to pattern depicted on figure below.



TENS Modality

Place the electrodes with the **RED** and **BLACK** ends of the lead wires according to pattern depicted on figure below.

Using both channels and crisscrossing the electrodes is optional when using the TENS modality.



Lateral / Medial Knee

PAIN CONTROL

INTENSITY LEVEL:

The stimulation level should be set to a strong, but comfortable strength.

DEVICE SET-UP:

Modality	Mode	Treatment Time
IFC	LoHi, Low, Cmb	40 minutes 4 times/day
TENS	Swp, Lmd, Hmd	As needed

ELECTRODE PLACEMENT

Electrodes should surround the targeted treatment site with area of pain located in the center of the electrode area.

IFC Modality

Place the electrodes with the **RED** and **BLACK** ends of the lead wires according to pattern depicted on figure below.



TENS Modality

Place the electrodes with the **RED** and **BLACK** ends of the lead wires according to pattern depicted on figure below. *Using both channels and crisscrossing the electrodes is optional when using the TENS modality.*



Anterior Knee

PAIN CONTROL

INTENSITY LEVEL:

The stimulation level should be set to a strong, but comfortable strength.

DEVICE SET-UP:

Modality	Mode	Treatment Time
IFC	LoHi, Low, Cmb	40 minutes 4 times/day
TENS	Swp, Lmd, Hmd	As needed

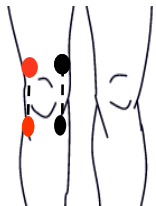
ELECTRODE PLACEMENT

Electrodes should surround the targeted treatment site with area of pain located in the center of the electrode area.



IFC Modality

Place the electrodes with the **RED** and **BLACK** ends of the lead wires according to pattern depicted on figure to the left.



TENS Modality

Place the electrodes with the **RED** and **BLACK** ends of the lead wires according to pattern depicted on figure to the left.

Using both channels and crisscrossing the electrodes is optional when using the TENS modality.

Wrist

PAIN CONTROL

INTENSITY LEVEL:

The stimulation level should be set to a strong, but comfortable strength.

DEVICE SET-UP:

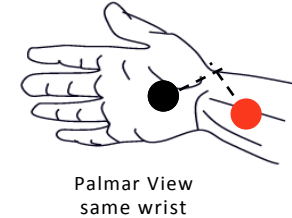
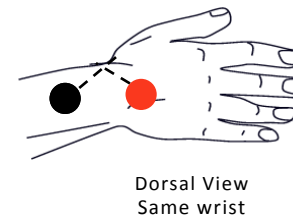
Modality	Mode	Treatment Time
IFC	LoHi, Low, Cmb	40 minutes 4 times/day
TENS	Swp, Lmd, Hmd	As needed

ELECTRODE PLACEMENT

Electrodes should surround the targeted treatment site with area of pain located in the center of the electrode area.

IFC Modality

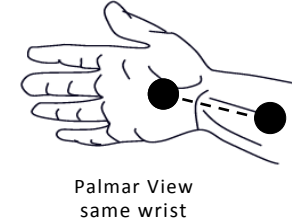
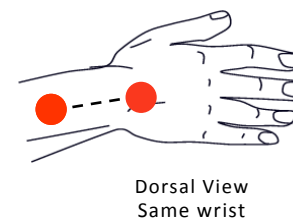
Place the electrodes with the **RED** and **BLACK** ends of the lead wires according to pattern depicted on figure below.



TENS Modality

Place the electrodes with the **RED** and **BLACK** ends of the lead wires according to pattern depicted on figure below.

Using both channels and crisscrossing the electrodes is optional when using the TENS modality.



Hip

PAIN CONTROL

INTENSITY LEVEL:

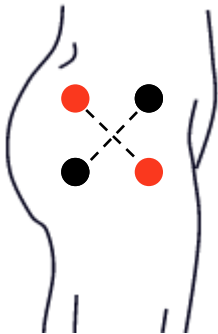
The stimulation level should be set to a strong, but comfortable strength.

DEVICE SET-UP:

Modality	Mode	Treatment Time
IFC	LoHi, Low, Cmb	40 minutes 4 times/day
TENS	Swp, Lmd, Hmd	As needed

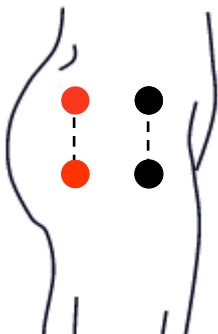
ELECTRODE PLACEMENT

Electrodes should surround the targeted treatment site with area of pain located in the center of the electrode area.



IFC Modality

Place the electrodes with the **RED** and **BLACK** ends of the lead wires according to pattern depicted on figure to the left.



TENS Modality

Place the electrodes with the **RED** and **BLACK** ends of the lead wires according to pattern depicted on figure to the left.

Using both channels and crisscrossing the electrodes is optional when using the TENS modality.

Back of Leg

PAIN CONTROL

INTENSITY LEVEL:

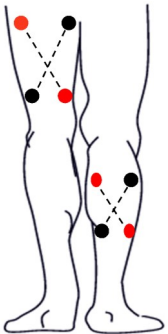
The stimulation level should be set to a strong, but comfortable strength.

DEVICE SET-UP:

Modality	Mode	Treatment Time
IFC	LoHi, Low, Cmb	40 minutes 4 times/day
TENS	Swp, Lmd, Hmd	As needed

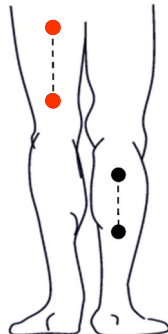
ELECTRODE PLACEMENT

Electrodes should surround the targeted treatment site with area of pain located in the center of the electrode area.



IFC Modality

Place the electrodes with the **RED** and **BLACK** ends of the lead wires according to pattern depicted on figure to the left.



TENS Modality

Place the electrodes with the **RED** and **BLACK** ends of the lead wires according to pattern depicted on figure to the left.

Using both channels and crisscrossing the electrodes is optional when using the TENS modality.